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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,099	01/10/2001	Michael Laposata	M0765/7034HCL/MAT	7656
7590	03/01/2005		EXAMINER	
Helen C. Lockhart Wolf, Greenfield & Sacks, P.C. Federal Reserve Plaza 600 Atlantic Avenue Boston, MA 02210-2211			COLE, MONIQUE T	
			ART UNJT	PAPER NUMBER
			1743	
			DATE MAILED: 03/01/2005	

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/758,099	LAPOSATA, MICHAEL	
	<b>Examiner</b>	<b>Art Unit</b>	
	Monique T. Cole	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 05 January 2005.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 28,29,31,35,45,95,117-139 and 176-178 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 35,45,95,121-139 and 176-178 is/are allowed.

6) Claim(s) 28, 29, 31 & 117-120 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____ .

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 28, 29, 31 & 117-120 rejected under 35 U.S.C. 103(a) as being unpatentable over "Fatty Acid Ethyl Esters: Ethanol Metabolites Which Mediate Ethanol-Induced Organ Damage and Serve As Markers of Ethanol Intake" by Laposata (herein referred to as "Laposata").

Laposata teaches that FAEE's correlate to the incidence of ethanol intake in liver and adipose tissue found in human subjects, particularly in infants and deceased individuals. FAEE's can serve as both a long term and short term marker of ethanol ingestion. FAEE's persist in the test samples for at least 24h after ethanol intake was completed. There is clinical utility for the FAEE measurement, as several algorithms have been developed to monitor ethanol intake.

See page 308, 1<sup>st</sup> full paragraph; page 313, last full paragraph; page 314, 3<sup>rd</sup> full paragraph-conclusion of the reference.

Laposata differs from the instantly claimed invention in that its determination of FAEE is not exclusive to liver & adipose tissue samples. However, since the instant claims are open to the inclusion of additional steps (i.e., "comprising" language), the claim would read on a method of determining the total FAEE derived from many sources such as the pancreas, liver, heart, brain and adipose tissue disclosed as sources of FAEE in Laposata. The total FAEE in Laposata would include an addition of the FAEE from all of these sources.

Laposata further differs from the instant claims in that it does not expressly disclose the amount of FAEE that is present in order to make the determination of ethanol intake. However, "it is the normal desire of scientists or artisans to improve upon what is already generally known." MPEP 2144.05.II.A. The Laposata reference makes a determination of heightened ethanol intake. This determination would require a comparison of the measured amount of FAEE in a subject to a known baseline amount of FAEE. It would necessarily follow that in order to diagnose heightened ethanol intake, an elevated range would be ascertained. Thus, it would have been obvious to one having ordinary skill in the art to modify the Laposata reference by selecting any number within the elevated range with the expectation that samples equaling or exceeding that amount would be reliable indicators of ethanol intake.

*Response to Arguments*

2. Applicant's remarks, see page 7, filed 1/5/2005, with respect to the rejection of claims 176-178 under 35 USC 112, 1<sup>st</sup> paragraph have been fully considered and are persuasive. The rejection of the claims has been withdrawn.
3. Applicant's arguments filed 1/5/2005 regarding the rejection of the claims under 35 USC 103 have been fully considered but they are not persuasive.

Applicant has argued that the Examiner has provided no basis for asserting that total FAEE would include an addition of the FAEE from all sources. The Examiner disagrees. See page 308, 1<sup>st</sup> full paragraph; page 313, last full paragraph; page 314, 3<sup>rd</sup> full paragraph-conclusion of the reference. Laposata clearly teaches that FAEE can serve as a marker and it further clearly teaches that FAEE can be derived from pancreas, liver, heart, brain and adipose tissue. The Laposata reference goes into detail when it teaches quantifying the FAEE in adipose tissue and blood and expressly teaches high concentrations of FAEE in the other body samples.

Applicant has argued that if the reference teaches determining FAEE from each of these sources, the Laposata reference still should not be applied against the claims because the instant claims require liver & adipose specifically. However, Laposata's disclosure would embrace the recited sources along with the other sources enumerated in the disclosure. The instant claims are not limited to just liver and adipose FAEE determination, but instead require at least the determination of FAEE from these two sources.

Applicant has taken issue with the Examiner's interpretation of "comprising" within the claim. However, the Laposata reference teaches the determination of FAEE from several

different sources, including liver and adipose tissue. Contrary Applicant's characterization of the reference, its disclosure is broad enough to encompass not only what is currently being claimed, but also additional steps/sources not required by the claims.

*Allowable Subject Matter*

4. Claims 35, 45, 95, 121-139 & 176-178 are allowed.
5. The following is a statement of reasons for the indication of allowable subject matter: the prior art does not teach or suggest that a ratio of the amount of total liver FAEE to the amount of total adipose FAEE of at least 2 is indicative of ethanol intake; the prior art does not teach or suggest ethyl arachidonate in at least 200 pmol/gram in the tissue, singularly, to indicate ethanol intake.
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1743

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monique T. Cole whose telephone number is 571-272-1255. The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*M. J. Cole*  
Monique T. Cole  
Primary Examiner  
Art Unit 1743

mtc